K011112

JUL 1 7 2001

DADE BEHRING

DADE BEHRING INC.
P.O. Box 6101
Newark, DE 19714

Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name: Lorraine Piestrak
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: April 10, 2001

Name of Product: Cyclosporine Calibrator

FDA Classification Name: Calibrator, Drug Specific

Predicate Device: EMIT® 2000 Cyclosporine Specific Calibrators

Device Description: The Dimension® Cyclosporine Calibrator is a frozen human whole blood product. The kit consists of six vials; two at level 1 and one each at levels 2 through 5.

Intended use: The Dimension® Cyclosporine Calibrator is intended to be used to calibrate the Cyclosporine (CSA) method on the Dimension® clinical chemistry system.

Comparison to Predicate Device:

	Dimension® System Cyclosporine Calibrator	EMIT® 2000 Cyclosporine Specific Calibrators
Intended Use	Calibrator	Calibrator
Analyte	Cyclosporine	Cyclosporine
Matrix	human whole blood base	human whole blood base
Form	frozen	frozen
Volume	2.5 mL per vial @ level 1 2.0 mL per vial @ levels 2-5	2.5 mL per vial @ level 1 2.0 mL per vial @ levels 2-5
Levels	5 levels @ 0, 80, 180, 330, 500 ng/ml	6 levels @ 0, 50, 100, 200, 350, 500 ng/ml

Comments on Substantial Equivalence: Both the EMIT® 200 Cyclosporine Specific Calibrators and the Dimension® Cyclosporine Calibrator are intended to be used as calibrators for Cyclosporine assays

Conclusion: The Dimension® Cyclosporine Calibrator is substantially equivalent to the EMIT® 200 Cyclosporine Specific Calibrators based on the comparison discussed above.

Lorraine Piestrak
Regulatory Affairs and Compliance Manager
April 10, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 17 2001

Ms. Lorrie Piestrak
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714

Re: 510(K) Number: K011112
Trade/Device Name: Cyclosporine Calibrator
Regulation Number: 862.3200
Regulatory Class: II
Product Code: DLJ
Dated: June 15, 2001
Received: June 18, 2001

Dear Ms. Piestrak:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

Device Name: Cyclosporine Calibrator

Indications for Use:

Cyclosporine Calibrator is an *in vitro* diagnostic product intended to be used to calibrate the Cyclosporine (CSA) method for the Dimension® clinical chemistry system. This product was designed to meet the needs of users to assure accurate results over the assay range of this method.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011112

Lorraine Piestrak
Regulatory Affairs and
Compliance Manager

April 10, 2001

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-counter Use**_____
(Per 21 CFR 801.109)